

United States Department of Agriculture Animal and Plant Health Inspection Service Plant Protection & Quarantine 4700 River Road Riverdale, MD 20737

Permit to Move Live Plant Pests, Noxious Weeds, and Soil

Interstate Movement

Regulated by 7 CFR 330

This 1	permit was	generated	electronicall	v via the	ePermits system

PERMITTEE NAME:Brian VaughanPERMIT NUMBER:P526P-18-01426ORGANIZATION:Monsanto, Agradis CampusAPPLICATION NUMBER:P526-180202-011ADDRESS:6650 Nancy Ridge DrFACILITY NUMBER:3546

ADDRESS: 6650 Nancy Ridge Dr FACILITY NUMBER: 3
San Diego, CA 92121

MAILING ADDRESS: 6650 Nancy Ridge Dr San Diego, CA 92121 HAND CARRY: No

PHONE: 619-368-1269 DATE ISSUED: 04/16/2018
DATE AMENDED: 05/01/2019
DATE AMENDED: 05/01/2019

FAX: EXPIRES: 04/16/2021

DESTINATION: 6650 Nancy Ridge Dr, San Diego, CA 92121

RELEASE: No

Under the conditions specified, this permit authorizes the following: **Originally Collected** Regulated <u>Life</u> **Intended Use Shipment Origins Culture** <u>Article</u> Stage(s) Designation Archaea Any Research - Growth AK, GU, HI, MP, PR, Originally Collected from Chamber (lab included) VI, Continental U.S. USA including territories Bacteria Research - Growth AK. GU. HI. MP. PR. Originally Collected from Any USA including territories Chamber (lab included) VI. Continental U.S. Fungi Research - Growth AK, GU, HI, MP, PR, Originally Collected from Any Chamber (lab included) VI, Continental U.S. USA including territories

PERMIT GUIDANCE

This permit does not authorize importation, interstate movement, possession, and/or use of strains of genetically engineered regulated organisms (created by the use of recombinant DNA technology).

This permit does not fulfill the requirements of other federal or state regulatory authorities. As appropriate, please contact the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the APHIS Veterinary Services unit, or your State's Department of Agriculture to ensure proper permitting.

If you are considering renewal of this permit, an application should be submitted at least 90 days prior to the expiration date of this permit to ensure continued coverage. Permits requiring containment

Permit Number P526P-18-01426

THIS PERMIT HAS BEEN APPROVED ELECTRONICALLY BY THE FOLLOWING PPQ HEADQUARTER OFFICIAL VIA EPERMITS.	DATE
Alaron.	
Osmond Baron	05/01/2019



facilities may take a longer period of time to process.

You must abide by all local quarantines see: http://www.aphis.usda.gov/planthealth/pests and diseases

Of special concern for movement of soil from certain continental areas are:

IMPORTED FIRE ANTS

http://www.aphis.usda.gov/plant-health/ifa

GOLDEN NEMATODES

http://www.aphis.usda.gov/planthealth/gn POTATO/PALE CYST NEMATODE

http://www.aphis.usda.gov/planthealth/pcn

PHYTOPHTHORA RAMORUM (Sudden Oak Death)

http://www.aphis.usda.gov/plant-health/sod

PERMIT CONDITIONS

This permit authorizes the interstate movement of soil and/or host plant materials (regulated material) from the continental U.S., HI, PR, and all U.S. territories for the isolation and identification of microorganisms (unidentified Archaea, Bacteria, Fungi). The permit is issued to Brian Vaughan of Monsanto, Agradis Campus, located at 6650 Nancy Ridge Dr., San Diego, CA 92121. This authorization is strictly for microbe isolation in a controlled laboratory and growth chamber environment. Plant and animal inoculations, and field research of plant pests or biocontrol organisms are not authorized under this permit (separate permits are required for such activities). Experiments with the regulated materials must be carried out in the inspected facility # 3546.

This permit authorizes the chemical and/or physical analysis procedures (including isolation of nucleic acids), typically authorized under a separate PPQ Form 525 permit, only if the operating procedures on file addressed those uses.

All operations must be consistent with information submitted in association with the above listed APHIS facility number.

1. Soil and infected plant material (The regulated material) must be packaged for Interstate movement in a securely closed, watertight primary container (e.g., test tube, vial, or ampule) that is completely enclosed in a second, durable watertight container (secondary container). Several primary containers may be enclosed in a single secondary container. The space between the primary and secondary containers must contain sufficient nonparticulate absorbent material (e.g., paper towel) to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers must be enclosed in an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

Permit Number P526P-18-01426

THIS PERMIT HAS BEEN APPROVED ELECTRONICALLY BY THE FOLLOWING PPQ HEADQUARTER OFFICIAL VIA EPERMITS.	DATE
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Osmond Baron	05/01/2019

WARNING: Any alteration, forgery or unauthorized use of this Federal Form is subject to civil penalties of up to \$250,000 (7 U.S.C.s 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C.s 1001)



You must instruct senders of the regulated material to double seal samples in heavy plastic bags (e.g. two zip-lock freezer bags), and to place the sealed bags in sturdy shipping container (e.g., Kraft paper or plastic shipping tubes/boxes).

- 2. All packages must be opened within a laminar flow biosafety cabinet (Class II, Type A). All isolations and culture transfers must be made in this biosafety cabinet.
- 3. All packing materials, shipping boxes, etc., which contained or were associated with soil or plant pests, must be sterilized or destroyed immediately after removing the regulated materials.
- 4. While in storage, all regulated material, and cultures will be kept locked (e.g. in freezer, cabinet), with access limited to authorized personnel or they will be in a restricted access building that requires a key card entry and access is restricted to authorized personnel only; or it will be in locked room restricted to authorized personnel only.
- 5. The permit holder or authorized individual must notify APHIS Plant Protection and Quarantine (PPQ) Pest Permitting Branch (PPB) within 10 working days of the confirmation that an organism is identified as (a) a species new to science, (b) an organism not known to occur in the United States, (c) a pathogen managed by an APHIS program (program pest; http://www.aphis.usda.gov/plant_health/plant_pest_info/index.shtml), or (d) a pathogen that is not widely prevalent in the State from which the infected material was obtained: (http://www.aphis.usda.gov/plant_health/permits/organism/wpp/index.shtml). Include the permit number, the origins and dates of receipt of the samples, and the identified organism. The notification must be sent to USDA/APHIS/PPQ/RPM/PPB, 4700 River Rd., Unit 133, Riverdale, MD 20737, faxed to 301-734-8700 or emailed to Pest.Permits@aphis.usda.gov Attn: Osmond Baron, as Word, Excel or pdf documents. Notifications must also be sent to the State Plant Health Director (SPHD) and State Plant Regulatory Official (SPRO) (of the state of origin of the specific sample) within 10 working days (see

http://www.aphis.usda.gov/services/report_pest_disease/report_pest_disease.shtml and http://www.nationalplantboard.org/member/index.html for contact information).

Plant pathogens isolated from materials received under this permit may be retained for laboratory use, if all of the following are met: (a) notification is provided to USDA-APHIS PPQ within ten days of confirmed identification of the organism(s), (b) a PPQ 526 application for research with the named organism(s) is received within 48 hours of the notification (section a), and (c) the organism is not listed as a program pest or a quarantine pest.

- 6. (a) Adequate protective clothing must be worn when working with soil and infected/infested samples so that movement of plant pests out of the facilities on hands, shirts, pants, and shoes does not occur.
 - (b) Laboratory flooring materials must be monolithic and consist of building materials that can be cleaned. Flooring materials must be maintained free of soil and defects that allow growth or survival of soil-borne pests.
 - (c) Work benches must consist of building materials that can be cleaned, and are maintained free of defects that allow growth or survival of soil-borne pests.

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DATE

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- (d) Disposable blotter materials used on workbench surfaces must autoclaved after each position of work is completed. Work surfaces must be appropriately cleaned between samples to reduce the potential for survival of soil-borne pests.
- (e) All source materials must be heat or chemically treated, on-site, sufficient to kill or render non-viable all life stages prior to disposal in municipal sewer or waste systems.
- (f) Any sink / laboratory water that may contain live nematode life stages (wastewater), infested soil, infested growing media, and infected plant materials (waste) must be equipped with traps that allow collection of waste water, and subsequent treatment of this wastewater kills or destroys all nematode life stages on-site prior to disposal in municipal sewer or waste systems.
- 7. Upon completion of research activities, all soil, infected plant material, and all cultures derived from these materials must be destroyed by autoclaving. Glassware and other materials used to conduct research must be decontaminated prior to reuse or disposal. These materials can either be (a) soaked in a fresh solution of 10 percent bleach (1:10v/v) for at least 30 minutes, (b) saturated with 70 percent ethanol, (c) flamed with ethanol, or (d) treated with quaternary ammonium compounds, until all microorganisms are dead or non-viable.
- 8. Plant and animal inoculations, and field research of plant pests or biocontrol organisms are not authorized in the greenhouse or field under this permit (separate permits are required for such activities).

Vector transmission is NOT permitted under this authorization.

9. All persons working with these organisms must be informed of these permit conditions. Anyone working with these organisms must agree to and sign/ initial these conditions before beginning work. These signed conditions do not need to be submitted to USDA/ APHIS but must be readily accessible in the event of an inspection and presented upon request.

Note: these conditions may be copied and stored electronically for electronic signature and initialing provided that the permit number, authorized organisms and life stages, release locations if applicable, and authorization statement all appear on the document with the permit number. Signing these conditions only indicates that the person working under this permit has read them; the permit holder is the sole responsible party under this permit.

10. Arthropod: (If included in samples):

All samples potentially containing mobile arthropod life stages must be placed in a refrigerator for at least 4 hours upon receipt and prior to opening in the Class II, Type A biological safety cabinet. Following this initial processing, living samples in sealed containers may be removed from the biosafety cabinet for subsequent diagnostic determinations.

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DATE

05/01/2019



11. Arthropod: (If included in samples):

Arthropod specimens that are either frozen, preserved in 70 percent alcohol, or preserved in another medium (e.g. fixed in glutaraldehyde) may be moved intra- and interstate without further permitting.

- 12. The permit holder must:
 - (a) comply with all requirements and permit conditions,
 - (b) maintain a valid permit so long as the regulated organisms are alive,
 - (c) not assign or transfer this permit to other persons,
 - (d) safeguard and dispose of the regulated organisms during the term of this permit,
 - (e) take all necessary precautions to prevent the unauthorized release of regulated organisms. In the event of an unauthorized release, the permit holder must notify the permit unit,
 - (f) adequately mitigate environmental impacts resulting from unauthorized release of regulated organisms,
 - (g) contain any/all organisms not authorized under this permit,
 - (h) notify the permit unit of the receipt of unauthorized organisms,
 - (i) notify the permit unit if facilities are destroyed or decommissioned for any reason,
 - (j) maintain an official permanent work assignment at the address on this permit,
 - (k) notify the permit unit in advance of any change in the permit holder's work assignment,
 - (l) destroy all regulated organisms prior to departure from the organization unless other arrangements are confirmed by the permit unit prior to parting, and
 - (m) notify the permit unit of the destruction of regulated organisms.

Notifications to the permit unit must be made via 866-524-5421 or pest.permits@aphis.usda.gov within one business day of the event triggering a notification.

- 13. There is to be no further distribution of these organisms without prior approval from State and Federal regulatory officials. A valid permit is required from both sender and receiver for interstate movement of the regulated materials.
- 14. Without prior notice and during reasonable hours, authorized PPQ and/or State regulatory officials shall be allowed to inspect the conditions associated with the regulated organisms authorized under this permit.
- 15. This permit does not authorize movement or use of plant pathogens listed in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. If any organism listed as a Select Agent is identified from materials associated with this research, the permit holder is required to notify APHIS, Agricultural Select Agent Program (ASAP) immediately by phone at 301-851-3300, and within seven (7) days submit APHIS/CDC Form 4 (Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory) to APHIS, ASAP; 4700 River Rd, Unit 2, Riverdale, MD 20737 (see instructions at:

Permit Number P526P-18-01426

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Osmond Baron	05/01/2019



- http://www.aphis.usda.gov/programs/ag_selectagent/index.shtml). Failure to comply with this requirement is a violation of the Agricultural Bioterrorism Protection Act of 2002.
- 16. Failure to comply with the terms and conditions of this permit may be cause for: (a) cancellation of this permit; (b) cancellation of other valid permits issued to the individual named as the holder of this permit; (c) seizure and destruction of permitted organisms; (d) denial of future permit applications made by the holder of this permit; (e) making the holder of this permit liable for civil penalties; and (f) subjecting the holder of this permit to criminal prosecution as provided in the Plant Protection Act.
- 17. Any alteration, forgery or unauthorized use of this permit and associated Federal Forms are subject to civil penalties of up to \$250,000 (7 U.S.C.s 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C.s 1001)
- 18. DEVITALIZATION AND WASTE DISPOSAL

All regulated materials/organisms and all items coming in direct contact or exposed to the regulated materials/organisms must be sterilized/sanitized/decontaminated prior to removal from the authorized containment facility. This includes all items from shipping, culturing, care, and maintenance of these regulated materials/organisms. This requirement includes but is not necessarily limited to: packaging directly exposed to the regulated materials/organisms, substrates (culture media, soil, plant materials (food materials or host plants)), leftover/unused/unneeded live cultures, and dead specimens/cultures unless specified otherwise in the permit.

Prior to disposal or reuse, you must treat all contaminated and all potentially contaminated materials by one of the following methods, either alone or in combination:

1) autoclaved (see protocol below), 2) disposed of off-site by a facility holding a valid PPQ compliance agreement (organisms and/or contaminated waste must be stored in sealed containers prior to pick up by this company), 3) incinerated, 4) immersed in 5,250-6,000 PPM sodium hypochlorite solution (1 part fresh household bleach to 9 parts water) for at least 20 minutes, or 5) immersed in 70 percent alcohol for at least 30 minutes.

Treated waste will be double bagged prior to disposal.

Other sterilization methods are only allowed with prior written agreement from the USDA/APHIS PPQ Pest Permit Staff.

If using an autoclave the following protocol must be used:

- a. Waste must be autoclaved at 121 Celsius (250 Fahrenheit) for a minimum of 30 minutes at 15 psi.
- b. Autoclave tape or other indicators must be placed on each load prior to treatment. The autoclave tape or other indicator on each container must be checked to verify color change before disposal.
- c. The autoclave must be calibrated according to the manufacturer's instructions annually and a

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commercially available biological indicator kit that uses bacterial spores of Geobacillus stearothermophilus that are rendered unviable at 121 Celsius (250 Fahrenheit) must be used every three months.

OR

The autoclave must be calibrated according to the manufacturer's instructions every two years and a commercially available biological indicator kit that uses bacterial spores of Geobacillus stearothermophilus that are rendered unviable at 121 Celsius (250 Fahrenheit) must be used every two weeks.

- d. A written record of the calibration and the biological indicator tests must be maintained. You must follow the manufacturer's instructions for the Geobacillus sterothermophilus and if any growth is observed, you must have the autoclave serviced and retested before it is used again for the regulated articles/organisms listed on this permit.
- 19. As an alternative to the DEVITALIZATION AND WASTE DISPOSAL requirements listed above, devitalization/destruction of organisms and infected material may be conducted off site by a facility holding a valid PPQ compliance agreement prior to disposal. Vendor may or may not be in the same state. All organisms, contaminants and/or packaging materials must be in sealed containers during transport to this waste management facility in order to prevent any unauthorized dissemination of the regulated articles.

END OF PERMIT CONDITIONS

	Permit Number P526P-18-01426
THIS PERMIT HAS BEEN APPROVED ELECTRONICALLY BY THE FOLLOWING	DATE
PPQ HEADQUARTER OFFICIAL VIA EPERMITS.	
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Osmond Baron	05/01/2019